

**Calendar No. 387**

108TH CONGRESS  
1ST SESSION

**S. 720**

**[Report No. 108–196]**

To amend title IX of the Public Health Service Act to provide for the improvement of patient safety and to reduce the incidence of events that adversely effect patient safety.

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IN THE SENATE OF THE UNITED STATES

MARCH 26, 2003

Mr. JEFFORDS (for himself, Mr. FRIST, Mr. BREAUX, Mr. GREGG, Mr. ENZI, Mr. HAGEL, and Mr. SMITH) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

NOVEMBER 17, 2003

Reported by Mr. GREGG, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italie*]

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**A BILL**

To amend title IX of the Public Health Service Act to provide for the improvement of patient safety and to reduce the incidence of events that adversely effect patient safety.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2       This Act may be cited as the “Patient Safety and  
3 Quality Improvement Act”.

4 **SEC. 2. FINDINGS AND PURPOSES.**

5       (a) **FINDINGS.**—Congress makes the following find-  
6 ings:

7           (1) In 1999, the Institute of Medicine released  
8 a report entitled *To Err is Human* that described  
9 medical errors as the eighth leading cause of death  
10 in the United States, with as many as 98,000 people  
11 dying as a result of medical errors each year.

12           (2) To address these deaths and injuries due to  
13 medical errors, the health care system must identify  
14 and learn from such errors so that systems of care  
15 can be improved.

16           (3) In their report, the Institute of Medicine  
17 called on Congress to provide legal protections with  
18 respect to information reported for the purposes of  
19 quality improvement and patient safety.

20           (4) The Health, Education, Labor, and Pen-  
21 sions Committee of the Senate held 4 hearings in  
22 the 106th Congress and 1 hearing in the 107th Con-  
23 gress on patient safety where experts in the field  
24 supported the recommendation of the Institute of  
25 Medicine for congressional action.

1           (5) Myriad public and private patient safety ini-  
2           tiatives have begun. The Quality Interagency Coordi-  
3           nation Taskforce has recommended steps to improve  
4           patient safety that may be taken by each Federal  
5           agency involved in health care and activities relating  
6           to these steps are ongoing.

7           (6) The research on patient safety unequivocally  
8           calls for a learning environment, rather than a  
9           punitive environment, in order to improve patient  
10          safety.

11          (7) Voluntary data gathering systems are more  
12          supportive than mandatory systems in creating the  
13          learning environment referred to in paragraph (5) as  
14          stated in the Institute of Medicine's report.

15          (8) Promising patient safety reporting systems  
16          have been established throughout the United States  
17          and the best ways to structure and use these sys-  
18          tems are currently being determined, largely through  
19          projects funded by the Agency for Healthcare Re-  
20          search and Quality.

21          (9) The Department of Health and Human  
22          Services has initiated several patient safety projects.  
23          The Joint Commission on Accreditation of  
24          Healthcare Organizations issued a patient safety  
25          standard that went into effect on July 1, 2001, and

1 the peer review organizations are conducting ongoing  
2 studies of clinical performance measurement of care  
3 delivered to beneficiaries under the medicare pro-  
4 gram under title XVIII of the Social Security Act.

5 (10) Many organizations currently collecting  
6 patient safety data have expressed a need for legal  
7 protections that will allow them to review protected  
8 information so that they may collaborate in the de-  
9 velopment and implementation of patient safety im-  
10 provement strategies. Currently, the State peer re-  
11 view protections provide inadequate conditions to  
12 allow the sharing of information to promote patient  
13 safety.

14 (11) In 2001, the Institute of Medicine released  
15 a report entitled Crossing the Quality Chasm that  
16 found that the United States health care system  
17 does not consistently deliver high quality care to pa-  
18 tients.

19 (b) PURPOSES.—It is the purpose of this Act to—

20 (1) encourage a culture of safety and quality in  
21 the United States health care system by providing  
22 for legal protection of information reported volun-  
23 tarily for the purposes of quality improvement and  
24 patient safety; and

1           (2) ensure accountability by raising standards  
 2           and expectations for continuous quality improve-  
 3           ments in patient safety through the actions of the  
 4           Secretary of Health and Human Services.

5 **SEC. 3. AMENDMENTS TO PUBLIC HEALTH SERVICE ACT.**

6           Title IX of the Public Health Service Act (42 U.S.C.  
 7           299 et seq.) is amended—

8           (1) in section 912(e), by inserting “, in accord-  
 9           ance with part C,” after “The Director shall”;

10           (2) by redesignating part C as part D;

11           (3) by redesignating sections 921 through 928,  
 12           as sections 931 through 938, respectively;

13           (4) in section 938(1) (as so redesignated), by  
 14           striking “921” and inserting “931”; and

15           (5) by inserting after part B the following:

16 **“PART C—PATIENT SAFETY IMPROVEMENT**

17 **“SEC. 921. DEFINITIONS.**

18           “In this part:

19           “(1) **NON-IDENTIFIABLE INFORMATION.**—The  
 20           term ‘non-identifiable information’ means informa-  
 21           tion that is presented in a form and manner that  
 22           prevents the identification of any provider, patient,  
 23           and the reporter of patient safety data.

24           “(2) **PATIENT SAFETY DATA.**—The term ‘pa-  
 25           tient safety data’ means—

1           “(A) any data, reports, records, memo-  
 2           randa, analyses, deliberative work, statements,  
 3           root cause analyses, or quality improvement  
 4           processes that could result in improved patient  
 5           safety or health care quality, that are—

6                   “(i) collected or developed by a pro-  
 7                   vider for the purpose of reporting to a pa-  
 8                   tient safety organization;

9                   “(ii) reported to a patient safety orga-  
 10                  nization for patient safety or quality im-  
 11                  provement processes;

12                  “(iii) requested by a patient safety or-  
 13                  ganization (including the contents of such  
 14                  request);

15                  “(iv) reported to a provider by a pa-  
 16                  tient safety organization;

17                  “(v) collected or developed by a pa-  
 18                  tient safety organization; or

19                  “(vi) reported among patient safety  
 20                  organizations, after obtaining authoriza-  
 21                  tion; or

22           “(B) information related to corrective ac-  
 23           tions taken in response to patient safety data;  
 24           for the purpose of improving patient safety, health  
 25           care quality, or health care outcomes.

1           “(3) ~~PATIENT SAFETY ORGANIZATION.~~—The  
2           term ‘patient safety organization’ means a private or  
3           public organization or component thereof that per-  
4           forms the following activities (which are deemed to  
5           be necessary for the proper management and admin-  
6           istration of such organization or component thereof):

7                   “(A) The conduct, as its primary activity,  
8                   of efforts to improve patient safety and the  
9                   quality of health care delivery.

10                   “(B) The collection and analysis of patient  
11                   safety data that are voluntarily submitted by a  
12                   provider.

13                   “(C) The development and dissemination  
14                   of information to providers with respect to im-  
15                   proving patient safety, such as recommenda-  
16                   tions, protocols, or information regarding best  
17                   practices.

18                   “(D) The utilization of patient safety data  
19                   to carry out activities under this paragraph and  
20                   for the purposes of encouraging a culture of  
21                   safety and of providing direct feedback and as-  
22                   sistance to providers to effectively minimize pa-  
23                   tient risk.

1           “(E) The maintenance of confidentiality  
2           with respect to individually identifiable health  
3           information.

4           “(F) The provision of appropriate security  
5           measures with respect to patient safety data.

6           “(G) The certification to the Agency that  
7           the patient safety organization satisfies the cri-  
8           teria of this paragraph for the period in which  
9           the organization is carrying out such duties.

10          “(4) PROVIDER.—The term ‘provider’ means—

11           “(A) a provider of services (as defined in  
12           section 1861(u) of the Social Security Act) and  
13           a person furnishing any medical or other health  
14           care services (as defined in section 1861(s)(1)  
15           and (2) of such Act) through, or under the au-  
16           thority of, such a provider of services;

17           “(B) a physician (as defined in section  
18           1861(r) of such Act);

19           “(C) any other person, including a phar-  
20           macist, who is engaged in the delivery of med-  
21           ical or other health services (as defined in sec-  
22           tion 1861(s)(1) and (2) of such Act) in a State  
23           and who is required by State law or regulation  
24           to be licensed or certified by the State to en-



1           gage in the delivery of such services in the  
2           State;

3                 ~~“(D) a renal dialysis facility; ambulatory~~  
4                 ~~surgical center; pharmacy; physician or health~~  
5                 ~~care practitioner’s office; long term care facility;~~  
6                 ~~behavioral health residential treatment facility;~~  
7                 ~~or clinical laboratory; or~~

8                 ~~“(E) any other person or entity specified~~  
9                 ~~in regulations by the Secretary after public no-~~  
10                ~~tice and comment.~~

11   ~~“SEC. 922. CONFIDENTIALITY AND PEER REVIEW PROTEC-~~  
12                 ~~TIONS.~~

13               ~~“(a) IN GENERAL.—Notwithstanding any other pro-~~  
14               ~~vision of law, and subject to this section, patient safety~~  
15               ~~data shall be privileged and confidential.~~

16               ~~“(b) SCOPE OF PRIVILEGE.—Subject to the provi-~~  
17               ~~sions of subsection (c), patient safety data to which sub-~~  
18               ~~section (a) applies shall not be—~~

19                     ~~“(1) subject to a civil, criminal, or administra-~~  
20                     ~~tive subpoena;~~

21                     ~~“(2) subject to discovery in connection with a~~  
22                     ~~civil, criminal, or administrative proceeding;~~

23                     ~~“(3) disclosed pursuant to section 552 of title~~  
24                     ~~5, United States Code (commonly known as the~~

1 Freedom of Information Act) or any other similar  
 2 Federal or State law;

3 “(4) admitted as evidence or otherwise disclosed  
 4 in any civil, criminal, or administrative proceeding;  
 5 or

6 “(5) utilized in an adverse employment action  
 7 or in the evaluation of decisions made in relation to  
 8 accreditation, certification, credentialing or licensing  
 9 of an individual, that is based on such individual’s  
 10 participation in the development, collection, report-  
 11 ing, or storage of patient safety data in accordance  
 12 with this part.

13 “(c) DISCLOSURE REQUIREMENTS.—Nothing in this  
 14 section shall be construed to prohibit one or more of the  
 15 following disclosures (which are deemed to be necessary  
 16 for the proper management and administration of the pa-  
 17 tient safety organization):

18 “(1) Disclosures by a provider in complying  
 19 with authorized requests for the provision of infor-  
 20 mation to which subsection (a) applies (such as a  
 21 patient’s medical record or other relevant informa-  
 22 tion) that is in the control of such a provider and  
 23 that has been developed, maintained, or exists sepa-  
 24 rately from the process by which the provider col-

1       lects or develops information for reporting to a pa-  
2       tient safety organization.

3           ~~“(2) Disclosures by a provider or patient safety~~  
4       ~~organization of patient safety data as part of a dis-~~  
5       ~~ciplinary proceeding relating to a provider, or a~~  
6       ~~criminal proceeding, if such a disclosure of such pa-~~  
7       ~~tient safety data is—~~

8                   ~~“(A) material to the proceeding;~~

9                   ~~“(B) within the public interest; and~~

10                  ~~“(C) not available from any other source.~~

11           ~~“(3) Disclosures by a provider or patient safety~~  
12       ~~organization of relevant information to the Food and~~  
13       ~~Drug Administration, or to a person that is subject~~  
14       ~~to the jurisdiction of such Administration, with re-~~  
15       ~~spect to an Administration-regulated product or ac-~~  
16       ~~tivity for which that entity has responsibility, for the~~  
17       ~~purposes of activities related to the quality, safety,~~  
18       ~~or effectiveness of such Administration-regulated~~  
19       ~~product or activity, subject to section 520(e) of the~~  
20       ~~Federal Food, Drug, and Cosmetic Act.~~

21           ~~“(4) Disclosures by a provider or patient safety~~  
22       ~~organization of information to which subsection (a)~~  
23       ~~applies to carry out activities described in paragraph~~  
24       ~~(2)(A) (i) through (vi) or (3) of section 921.~~

1       “(d) **TRANSFER OF INFORMATION.**—The transfer of  
 2 any patient safety data by a provider to a patient safety  
 3 organization shall not be treated as a waiver of any privi-  
 4 lege or protection established under this part or estab-  
 5 lished under State law.

6       “(e) **PENALTY.**—Except as provided in subsection (e)  
 7 and as otherwise provided for in this section, it shall be  
 8 unlawful for any person to disclose any patient safety data  
 9 described in subsection (a). Any person violating the provi-  
 10 sions of this section shall, upon conviction, be fined in ac-  
 11 cordance with section 934(d).

12       “(f) **NO LIMITATION OF OTHER PRIVILEGES.**—Noth-  
 13 ing in this section shall be construed to limit other privi-  
 14 leges that are available under Federal or State laws that  
 15 provide greater peer review or confidentiality protections  
 16 than the peer review and confidentiality protections pro-  
 17 vided for in this section.

18       “(g) **RULE OF CONSTRUCTION.**—Nothing in this sec-  
 19 tion shall be construed to alter or affect the implementa-  
 20 tion of any provision of section 264(e) of the Health Insur-  
 21 ance Portability and Accountability Act of 1996 (Public  
 22 Law 104–191; 110 Stat. 2033) or any regulation promul-  
 23 gated under such section.

24       **“SEC. 923. NATIONAL DATABASE.**

25       “(a) **AUTHORITY.**—

1           “(1) IN GENERAL.—In conducting activities  
2           under this part, the Secretary may provide for the  
3           establishment and maintenance of a database to re-  
4           ceive relevant non-identifiable patient safety data, or  
5           may designate entities to collect relevant non-identi-  
6           fiable patient safety data, that is voluntarily re-  
7           ported by patient safety organizations upon the re-  
8           quest of the Secretary.

9           “(2) USE OF DATA.—Data reported to any  
10          database established or designated under paragraph  
11          (1) shall be used to analyze regional variations and  
12          national statistics related to patient safety and  
13          health care quality. The information resulting from  
14          such analyses may be included in the annual quality  
15          reports prepared under section 913(b)(2).

16          “(b) STANDARDS.—In developing or designating a  
17          database under subsection (a)(1), the Secretary may de-  
18          termine common formats for the voluntary reporting of  
19          non-identifiable patient safety data, including necessary  
20          data elements, common and consistent definitions, and a  
21          standardized computer interface for the processing of such  
22          data. To the extent practicable, such standards shall be  
23          consistent with the administrative simplification provisions  
24          of part C of title XI of the Social Security Act.

1       ~~“(c) CONFIDENTIALITY.—Any non-identifiable pa-~~  
 2     ~~tient safety data that is transferred to the database under~~  
 3     ~~this section shall be privileged and confidential.~~

4     ~~“SEC. 924. TECHNICAL ASSISTANCE.~~

5       ~~“The Secretary, acting through the Director, may~~  
 6     ~~provide technical assistance to patient safety organiza-~~  
 7     ~~tions. Such assistance shall include annual meetings for~~  
 8     ~~patient safety organizations to discuss methodology, com-~~  
 9     ~~munication, data collection, or privacy concerns.~~

10   ~~“SEC. 925. PROMOTING THE INTEGRATION OF HEALTH~~  
 11       ~~CARE INFORMATION TECHNOLOGY SYSTEMS.~~

12       ~~“(a) DEVELOPMENT.—Not later than 36 months~~  
 13     ~~after the date of enactment of the Patient Safety and~~  
 14     ~~Quality Improvement Act, the Secretary shall develop or~~  
 15     ~~adopt voluntary national standards that promote the inte-~~  
 16     ~~gration of health care information technology systems.~~

17       ~~“(b) UPDATES.—The Secretary shall provide for the~~  
 18     ~~ongoing review and periodic updating of the standards de-~~  
 19     ~~veloped under subsection (a).~~

20       ~~“(c) DISSEMINATION.—The Secretary shall provide~~  
 21     ~~for the dissemination of the standards developed and up-~~  
 22     ~~dated under this section.~~

23   ~~“SEC. 926. AUTHORIZATION OF APPROPRIATIONS.~~

24       ~~“There is authorized to be appropriated such sums~~  
 25     ~~as may be necessary to carry out this part.”.~~

1 **SEC. 4. STUDIES AND REPORTS.**

2 (a) **MEDICAL TECHNOLOGIES AND THERAPIES.—**

3 (1) **IN GENERAL.**—The Secretary of Health and  
4 Human Services shall enter into a contract with an  
5 appropriate research organization for the conduct of  
6 a study to assess the impact of medical technologies  
7 and therapies on patient safety, patient benefit,  
8 health care quality, and the costs of care as well as  
9 productivity growth. Such study shall determine—

10 (A) the extent to which the current health  
11 care system's use of labor versus the use of  
12 technology has contributed to increases in the  
13 share of the gross domestic product that is de-  
14 voted to health care and the impact of medical  
15 technologies and therapies on such increases;

16 (B) the extent to which early and appro-  
17 priate introduction and integration of innovative  
18 medical technologies and therapies may affect  
19 the overall productivity and quality of the  
20 health care delivery systems of the United  
21 States; and

22 (C) the relationship of such medical tech-  
23 nologies and therapies to patient safety, patient  
24 benefit, health care quality, and cost of care.

25 (2) **REPORT.**—Not later than 18 months after  
26 the date of enactment of this Act, the Secretary of

1 Health and Human Services shall prepare and sub-  
 2 mit to the appropriate committees of Congress a re-  
 3 port containing the results of the study conducted  
 4 under paragraph (1).

5 (b) STATE LAWS RELATING TO PATIENT SAFETY  
 6 PEER REVIEW SYSTEMS.—

7 (1) SURVEY.—The Attorney General shall con-  
 8 duct a survey of State laws that relate to patient  
 9 safety data peer review systems, including laws that  
 10 establish an evidentiary privilege applicable to data  
 11 developed by such systems, and shall review the  
 12 manner in which such laws have been interpreted by  
 13 the courts.

14 (2) REPORT.—Not later than 9 months after  
 15 the date of enactment of this Act, the Attorney Gen-  
 16 eral shall prepare and submit to the Committee on  
 17 Health, Education, Labor, and Pensions of the Sen-  
 18 ate and the Committee on Energy and Commerce of  
 19 the House of Representatives, a report concerning  
 20 the results of the survey conducted under paragraph  
 21 (1).

22 **SECTION 1. SHORT TITLE.**

23 *This Act may be cited as the “Patient Safety and*  
 24 *Quality Improvement Act of 2003”.*



1 **SEC. 2. FINDINGS AND PURPOSES.**

2 (a) *FINDINGS.*—Congress makes the following findings:

3 (1) *In 1999, the Institute of Medicine released a*  
4 *report entitled To Err is Human that described med-*  
5 *ical errors as the eighth leading cause of death in the*  
6 *United States, with as many as 98,000 people dying*  
7 *as a result of medical errors each year.*

8 (2) *To address these deaths and injuries due to*  
9 *medical errors, the health care system must identify*  
10 *and learn from such errors so that systems of care can*  
11 *be improved.*

12 (3) *In their report, the Institute of Medicine*  
13 *called on Congress to provide legal protections with*  
14 *respect to information reported for the purposes of*  
15 *quality improvement and patient safety.*

16 (4) *The Health, Education, Labor, and Pensions*  
17 *Committee of the Senate held 4 hearings in the 106th*  
18 *Congress and 1 hearing in the 107th Congress on pa-*  
19 *tient safety where experts in the field supported the*  
20 *recommendation of the Institute of Medicine for con-*  
21 *gressional action.*

22 (5) *Myriad public and private patient safety*  
23 *initiatives have begun. The Quality Interagency Co-*  
24 *ordination Taskforce has recommended steps to im-*  
25 *prove patient safety that may be taken by each Fed-*

1        *eral agency involved in health care and activities re-*  
 2        *lating to these steps are ongoing.*

3            *(6) The research on patient safety unequivocally*  
 4        *calls for a learning environment, rather than a puni-*  
 5        *tive environment, in order to improve patient safety.*

6            *(7) Voluntary data gathering systems are more*  
 7        *supportive than mandatory systems in creating the*  
 8        *learning environment referred to in paragraph (6) as*  
 9        *stated in the Institute of Medicine's report.*

10          *(8) Promising patient safety reporting systems*  
 11        *have been established throughout the United States*  
 12        *and the best ways to structure and use these systems*  
 13        *are currently being determined, largely through*  
 14        *projects funded by the Agency for Healthcare Research*  
 15        *and Quality.*

16          *(9) Many organizations currently collecting pa-*  
 17        *tient safety data have expressed a need for legal pro-*  
 18        *tections that will allow them to review protected in-*  
 19        *formation and collaborate in the development and im-*  
 20        *plementation of patient safety improvement strate-*  
 21        *gies. Currently, the State peer review protections are*  
 22        *inadequate to allow the sharing of information to pro-*  
 23        *mote patient safety.*

24        *(b) PURPOSES.—It is the purpose of this Act to—*

1           (1) *encourage a culture of safety and quality in*  
 2           *the United States health care system by providing for*  
 3           *legal protection of information reported voluntarily*  
 4           *for the purposes of quality improvement and patient*  
 5           *safety; and*

6           (2) *ensure accountability by raising standards*  
 7           *and expectations for continuous quality improvements*  
 8           *in patient safety.*

9   **SEC. 3. AMENDMENTS TO PUBLIC HEALTH SERVICE ACT.**

10       *Title IX of the Public Health Service Act (42 U.S.C.*  
 11       *299 et seq.) is amended—*

12           (1) *in section 912(c), by inserting “, in accord-*  
 13           *ance with part C,” after “The Director shall”;*

14           (2) *by redesignating part C as part D;*

15           (3) *by redesignating sections 921 through 928, as*  
 16           *sections 931 through 938, respectively;*

17           (4) *in 934(d) (as so redesignated), by striking*  
 18           *the second sentence and inserting the following: “Pen-*  
 19           *alties provided for under this section shall be imposed*  
 20           *and collected by the Secretary using the administra-*  
 21           *tive and procedural processes used to impose and col-*  
 22           *lect civil money penalties under section 1128A of the*  
 23           *Social Security Act (other than subsections (a) and*  
 24           *(b), the second sentence of subsection (f), and sub-*  
 25           *sections (i), (m), and (n)), unless the Secretary deter-*

1        *mines that a modification of procedures would be*  
 2        *more suitable or reasonable to carry out this sub-*  
 3        *section and provides for such modification by regula-*  
 4        *tion.”;*

5            *(5) in section 938(1) (as so redesignated), by*  
 6        *striking “921” and inserting “931”; and*

7            *(6) by inserting after part B the following:*

8        **“PART C—PATIENT SAFETY IMPROVEMENT**

9        **“SEC. 921. DEFINITIONS.**

10        *“In this part:*

11            *“(1) NON-IDENTIFIABLE INFORMATION.—*

12            *“(A) IN GENERAL.—The term ‘non-identifi-*  
 13        *able information’ means information that is pre-*  
 14        *sented in a form and manner that prevents the*  
 15        *identification of a provider, a patient, or a re-*  
 16        *porter of patient safety data.*

17            *“(B) IDENTIFIABILITY OF PATIENT.—For*  
 18        *purposes of subparagraph (A), the term ‘pre-*  
 19        *sented in a form and manner that prevents the*  
 20        *identification of a patient’ means, with respect*  
 21        *to information that has been subject to rules pro-*  
 22        *mulgated pursuant to section 264(c) of the*  
 23        *Health Insurance Portability and Accountability*  
 24        *Act of 1996 (42 U.S.C. 1320d–2 note), that the*  
 25        *information has been de-identified so that it is*

1           *no longer individually identifiable health infor-*  
 2           *mation as defined in such rules.*

3           “(2) *PATIENT SAFETY DATA.*—

4                 “(A) *IN GENERAL.*—*The term ‘patient safe-*  
 5           *ty data’ means—*

6                         “(i) *any data, reports, records, memo-*  
 7                         *randa, analyses (such as root cause anal-*  
 8                         *yses), or statements that could result in im-*  
 9                         *proved patient safety or health care quality*  
 10                         *or health care outcomes, that are—*

11                                 “(I) *collected or developed by a*  
 12                                 *provider for reporting to a patient*  
 13                                 *safety organization, provided that they*  
 14                                 *are reported to the patient safety orga-*  
 15                                 *nization within a reasonable period of*  
 16                                 *time;*

17                                 “(II) *requested by a patient safety*  
 18                                 *organization (including the contents of*  
 19                                 *such request);*

20                                 “(III) *reported to a provider by a*  
 21                                 *patient safety organization; or*

22                                 “(IV) *collected from a provider or*  
 23                                 *patient safety organization or devel-*  
 24                                 *oped by a patient safety organization;*  
 25                                 *or*

1                   “(ii) any deliberative work or process  
2                   or oral communications with respect to any  
3                   patient safety data described in clause (i).

4                   “(B) *LIMITATION.*—The term ‘patient safety  
5                   data’ shall not include information (including a  
6                   patient’s medical record) that is collected or de-  
7                   veloped separately from and that exists sepa-  
8                   rately from patient safety data. Such separate  
9                   information or a copy thereof submitted to a pa-  
10                  tient safety organization shall not itself be con-  
11                  sidered as patient safety data.

12                  “(3) *PATIENT SAFETY ORGANIZATION.*—The term  
13                  ‘patient safety organization’ means a private or pub-  
14                  lic organization or component thereof that performs  
15                  all of the following activities (which are deemed to be  
16                  necessary for the proper management and adminis-  
17                  tration of such organization or component thereof),  
18                  and that is currently listed by the Secretary as a pa-  
19                  tient safety organization pursuant to section 924(c):

20                  “(A) The conduct, as its primary activity,  
21                  of efforts to improve patient safety and the qual-  
22                  ity of health care delivery.

23                  “(B) The collection and analysis of patient  
24                  safety data that are submitted by more than one  
25                  provider.

1           “(C) *The development and dissemination of*  
 2           *information to providers with respect to improv-*  
 3           *ing patient safety, such as recommendations,*  
 4           *protocols, or information regarding best prac-*  
 5           *tices.*

6           “(D) *The utilization of patient safety data*  
 7           *for the purposes of encouraging a culture of safe-*  
 8           *ty and of providing direct feedback and assist-*  
 9           *ance to providers to effectively minimize patient*  
 10          *risk.*

11          “(E) *The maintenance of a process to pre-*  
 12          *serve confidentiality with respect to the informa-*  
 13          *tion that is not non-identifiable.*

14          “(F) *The provision of appropriate security*  
 15          *measures with respect to patient safety data.*

16          “(G) *The submittal to the Secretary of a*  
 17          *certification pursuant to section 924.*

18          “(4) *PROVIDER.—The term ‘provider’ means—*

19               “(A) *a person licensed or otherwise author-*  
 20               *ized under State law to provide health care serv-*  
 21               *ices, including—*

22                       “(i) *a hospital, nursing facility, com-*  
 23                       *prehensive outpatient rehabilitation facility,*  
 24                       *home health agency, hospice program, renal*  
 25                       *dialysis facility, ambulatory surgical center,*

pharmacy, physician or health care practitioner's office, long term care facility, behavior health residential treatment facility, clinical laboratory, or health center; or

“(ii) a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner; or

“(B) any other person specified in regulations promulgated by the Secretary.

**“SEC. 922. PRIVILEGE AND CONFIDENTIALITY PROTECTIONS.**

“(a) *PRIVILEGE*.—Notwithstanding any other provision of Federal, State, or local law, patient safety data shall be privileged and, subject to the provisions of subsection (c), shall not be—

“(1) subject to a Federal, State, or local civil, criminal, or administrative subpoena;

“(2) subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding;



1           “(3) disclosed pursuant to section 552 of title 5,  
 2           *United States Code (commonly known as the Freedom*  
 3           *of Information Act) or any other similar Federal,*  
 4           *State, or local law;*

5           “(4) admitted as evidence or otherwise disclosed  
 6           *in any Federal, State, or local civil, criminal, or ad-*  
 7           *ministrative proceeding; or*

8           “(5) utilized in a disciplinary proceeding  
 9           *against a provider.*

10          “(b) *CONFIDENTIALITY.*—Notwithstanding any other  
 11          *provision of Federal, State, or local law, and subject to the*  
 12          *provisions of subsections (c) and (d), patient safety data*  
 13          *shall be confidential and shall not be disclosed.*

14          “(c) *EXCEPTIONS TO PRIVILEGE AND CONFIDEN-*  
 15          *TIALITY.*—Nothing in this section shall be construed to pro-  
 16          hibit one or more of the following uses or disclosures:

17               “(1) Disclosure by a provider or patient safety  
 18               organization of relevant patient safety data for use in  
 19               a criminal proceeding only after a court makes an in  
 20               camera determination that such patient safety data  
 21               contains evidence of an intentional act to directly  
 22               harm the patient.

23               “(2) Voluntary disclosure by a provider or pa-  
 24               tient safety organization of information to the Food  
 25               and Drug Administration, or to a person that is sub-

1     *ject to the jurisdiction of the Food and Drug Admin-*  
 2     *istration, with respect to a Food and Drug Adminis-*  
 3     *tration-regulated product or activity for which that*  
 4     *entity has responsibility, for the purposes of activities*  
 5     *related to the quality, safety, or effectiveness of a Food*  
 6     *and Drug Administration-regulated product or activ-*  
 7     *ity or a Food and Drug Administration proceeding.*

8             *“(3) Voluntary disclosure of non-identifiable pa-*  
 9     *tient safety data by a provider or a patient safety or-*  
 10    *ganization.*

11            *“(4) Voluntary disclosure by a provider of pa-*  
 12    *tient safety data to the Centers for Disease Control*  
 13    *and Prevention for public health surveillance, inves-*  
 14    *tigation, or other public health activities.*

15            *“(d) PROTECTED DISCLOSURE AND USE OF INFORMA-*  
 16    *TION.—Nothing in this section shall be construed to prohibit*  
 17    *one or more of the following uses or disclosures:*

18            *“(1) Disclosure by a provider or patient safety*  
 19    *organization of information to which subsections (a)*  
 20    *or (b) applies to carry out activities described in*  
 21    *paragraph (2) or (3) of section 921.*

22            *“(2) Use or disclosure by a provider or patient*  
 23    *safety organization of patient safety data in connec-*  
 24    *tion with providing treatment, improving patient*  
 25    *safety, health care quality or administrative effi-*

1       *ciency, or any other customary activity of the pro-*  
 2       *vider or in obtaining payment.*

3               “(3) *Disclosure of patient safety data among pa-*  
 4       *tient safety organizations.*

5               “(4) *Disclosure of patient safety data by a pro-*  
 6       *vider or patient safety organization to grantees or*  
 7       *contractors carrying out patient safety research, eval-*  
 8       *uation, or demonstration projects authorized by the*  
 9       *Director.*

10              “(5) *Disclosure of patient safety data by a pro-*  
 11       *vider to an accrediting body that accredits that pro-*  
 12       *vider.*

13              “(e) *CONTINUED PROTECTION OF INFORMATION.—Pa-*  
 14       *tient safety data used or disclosed in accordance with sub-*  
 15       *section (d) shall continue to be privileged and confidential*  
 16       *in accordance with subsections (a) and (b) and shall not*  
 17       *be disclosed—*

18              “(1) *by an entity that possessed such informa-*  
 19       *tion before such use or disclosure; or*

20              “(2) *by an entity to which the information was*  
 21       *disclosed;*

22       *unless such additional disclosure is permitted under sub-*  
 23       *section (d).*

24              “(f) *LIMITATION ON ACTIONS.—*

1           “(1) *PATIENT SAFETY ORGANIZATIONS.*—*Except*  
 2           *as provided in subsection (c), no action may be*  
 3           *brought or process served against a patient safety or-*  
 4           *ganization to compel disclosure of information col-*  
 5           *lected or developed under this part whether or not*  
 6           *such information is patient safety data.*

7           “(2) *PROVIDERS.*—*An accrediting body shall not*  
 8           *take an accrediting action against a provider based*  
 9           *on the good faith participation of the provider in the*  
 10           *collection, development, reporting, or maintenance of*  
 11           *patient safety data in accordance with this part. An*  
 12           *accrediting body may not require a provider to reveal*  
 13           *its communications with any patient safety organiza-*  
 14           *tion established in accordance with this part.*

15           “(g) *DISCLOSURE OR USE OF INFORMATION.*—

16           “(1) *IN GENERAL.*—*Except with respect to the*  
 17           *specific patient safety data that is used or disclosed,*  
 18           *the disclosure or use of any patient safety data in ac-*  
 19           *cordance with subsection (c) or (d) shall not be treat-*  
 20           *ed as a waiver of any privilege or protection estab-*  
 21           *lished under this part.*

22           “(2) *INADVERTENT DISCLOSURE OR USE.*—*The*  
 23           *inadvertent disclosure or use of patient safety data*  
 24           *shall not waive any privilege or protection established*  
 25           *under this part with respect to such data.*

1       “(h) *REPORTER PROTECTION.*—

2               “(1) *IN GENERAL.*—A provider may not take an  
3       adverse employment action, as described in para-  
4       graph (2), against an individual based upon the fact  
5       that the individual in good faith reported informa-  
6       tion—

7               “(A) to the provider with the intention of  
8       having the information reported to a patient  
9       safety organization; or

10              “(B) directly to a patient safety organiza-  
11       tion.

12              “(2) *ADVERSE EMPLOYMENT ACTION.*—For pur-  
13       poses of this subsection, an ‘adverse employment ac-  
14       tion’ includes—

15              “(A) loss of employment, the failure to pro-  
16       mote an individual, or the failure to provide any  
17       other employment-related benefit for which the  
18       individual would otherwise be eligible; or

19              “(B) an adverse evaluation or decision  
20       made in relation to accreditation, certification,  
21       credentialing, or licensing of the individual.

22       “(i) *ENFORCEMENT.*—

23              “(1) *PROHIBITION.*—Except as provided in sub-  
24       sections (c) and (d) and as otherwise provided for in  
25       this section, it shall be unlawful for any person to

1 *negligently or intentionally disclose any patient safe-*  
 2 *ty data described in subsection (a) and any such per-*  
 3 *son shall, upon adjudication, be assessed in accord-*  
 4 *ance with section 934(d).*

5 “(2) *RELATION TO HIPAA.*—*The penalty pro-*  
 6 *vided for under paragraph (1) shall not apply if the*  
 7 *defendant would otherwise be subject to a penalty*  
 8 *under the regulations promulgated under section*  
 9 *264(c) of the Health Insurance Portability and Ac-*  
 10 *countability Act of 1996 (42 U.S.C. 1320d–2 note) or*  
 11 *under section 1176 of the Social Security Act (42*  
 12 *U.S.C. 1320d–5) for the same disclosure.*

13 “(3) *EQUITABLE RELIEF.*—*Without limiting*  
 14 *remedies available to other parties, a civil action may*  
 15 *be brought by any aggrieved individual to enjoin any*  
 16 *act or practice that violates subsection (h) and to ob-*  
 17 *tain other appropriate equitable relief (including re-*  
 18 *instatement, back pay, and restoration of benefits) to*  
 19 *redress such violation.*

20 “(4) *ACTIONS AGAINST STATE EMPLOYEES.*—  
 21 *Notwithstanding subsection (a), with respect to a*  
 22 *State employer, the privilege described in such sub-*  
 23 *section shall not apply to such employer unless the*  
 24 *employer consents, in advance, to be subject to a civil*  
 25 *action under paragraph (3).*

1       “(j) *RULE OF CONSTRUCTION.*—*Nothing in this sec-*  
 2   *tion shall be construed to—*

3               “(1) *limit other privileges that are available*  
 4   *under Federal, State, or local laws that provide great-*  
 5   *er confidentiality protections or privileges than the*  
 6   *privilege and confidentiality protections provided for*  
 7   *in this section;*

8               “(2) *limit, alter, or affect the requirements of*  
 9   *Federal, State, or local law pertaining to patient-re-*  
 10   *lated data that is not privileged or confidential under*  
 11   *this section;*

12              “(3) *alter or affect the implementation of any*  
 13   *provision of section 264(c) of the Health Insurance*  
 14   *Portability and Accountability Act of 1996 (Public*  
 15   *Law 104–191; 110 Stat. 2033), section 1176 of the*  
 16   *Social Security Act (42 U.S.C. 1320d–5), or any reg-*  
 17   *ulation promulgated under such sections;*

18              “(4) *limit the authority of any provider, patient*  
 19   *safety organization, or other person to enter into a*  
 20   *contract requiring greater confidentiality or dele-*  
 21   *gating authority to make a disclosure or use in ac-*  
 22   *cordance with subsection (c) or (d); and*

23              “(5) *prohibit a provider from reporting crime to*  
 24   *law enforcement authorities.*

1 **“SEC. 923. PATIENT SAFETY NETWORK OF DATABASES.**

2       “(a) *IN GENERAL.*—*The Secretary shall maintain a*  
 3 *patient safety network of databases that provides an inter-*  
 4 *active evidence-based management resource for providers,*  
 5 *patient safety organizations, and other persons. The net-*  
 6 *work of databases shall have the capacity to accept, aggre-*  
 7 *gate, and analyze nonidentifiable patient safety data volun-*  
 8 *tarily reported by patient safety organizations, providers,*  
 9 *or other persons.*

10       “(b) *NETWORK OF DATABASE STANDARDS.*—*The Sec-*  
 11 *retary may determine common formats for the reporting to*  
 12 *the patient safety network of databases maintained under*  
 13 *subsection (a) of nonidentifiable patient safety data, includ-*  
 14 *ing necessary data elements, common and consistent defini-*  
 15 *tions, and a standardized computer interface for the proc-*  
 16 *essing of such data. To the extent practicable, such stand-*  
 17 *ards shall be consistent with the administrative simplifica-*  
 18 *tion provisions of part C of title XI of the Social Security*  
 19 *Act.*

20 **“SEC. 924. PATIENT SAFETY ORGANIZATION CERTIFI-**  
 21 **CATION AND LISTING.**

22       “(a) *CERTIFICATION.*—

23       “(1) *INITIAL CERTIFICATION.*—*Except as pro-*  
 24 *vided in paragraph (2), an entity that seeks to be a*  
 25 *patient safety organization shall submit an initial*  
 26 *certification to the Secretary that the entity intends*



1       to perform the activities described in subparagraphs  
2       (A) through (F) of section 921(3).

3               “(2) *DELAYED CERTIFICATION OF COLLECTION*  
4       *FROM MORE THAN ONE PROVIDER.*—An entity that  
5       seeks to be a patient safety organization may—

6               “(A) submit an initial certification that it  
7       intends to perform the activities described in  
8       subparagraph (A) through (F) of section 921(3)  
9       other than the activities described in subpara-  
10      graph (B) of such section; and

11              “(B) within 2 years of submitting the ini-  
12      tial certification under subparagraph (A), sub-  
13      mit a supplemental certification that it performs  
14      the activities described in section 921(3)(B).

15              “(3) *EXPIRATION AND RENEWAL.*—

16              “(A) *EXPIRATION.*—An initial certification  
17      under paragraph (1) or (2)(A) shall expire on  
18      the date that is 3 years after it is submitted.

19              “(B) *RENEWAL.*—

20              “(i) *IN GENERAL.*—An entity that  
21      seeks to remain a patient safety organiza-  
22      tion after the expiration of an initial cer-  
23      tification under paragraph (1) or (2)(A)  
24      shall, within the 3-year period described in  
25      subparagraph (A), submit a renewal certifi-

1                    *cation to the Secretary that the entity satis-*  
 2                    *fies the criteria described in subparagraph*  
 3                    *(A) through (F) of section 921(3).*

4                    *“(ii) TERM OF RENEWAL.—A renewal*  
 5                    *certification under clause (i) shall expire on*  
 6                    *the date that is 3 years after that date on*  
 7                    *which it is submitted, and may be renewed*  
 8                    *in the same manner as an initial certifi-*  
 9                    *cation.*

10                  *“(b) ACCEPTANCE OF CERTIFICATION.—Upon the sub-*  
 11                  *mission by an organization of an initial certification pur-*  
 12                  *suant to subsection (a)(1) or (a)(2)(A), a supplemental cer-*  
 13                  *tification pursuant to subsection (a)(2)(B), or a renewal*  
 14                  *certification pursuant to subsection (a)(3)(B), the Secretary*  
 15                  *shall review such certification and—*

16                  *“(1) if such certification meets the requirements*  
 17                  *of subsection (a)(1) or (a)(2)(A), (a)(2)(B), or*  
 18                  *(a)(3)(B), as applicable, the Secretary shall notify the*  
 19                  *organization that such certification is accepted; or*

20                  *“(2) if such certification does not meet such re-*  
 21                  *quirements, as applicable, the Secretary shall notify*  
 22                  *the organization that such certification is not accept-*  
 23                  *ed and the reasons therefore.*

24                  *“(c) LISTING.—*

1           “(1) *IN GENERAL.*—*Except as otherwise provided*  
 2           *in this subsection, the Secretary shall compile and*  
 3           *maintain a current listing of patient safety organiza-*  
 4           *tions with respect to which the Secretary has accepted*  
 5           *a certification pursuant to subsection (b).*

6           “(2) *REMOVAL FROM LISTING.*—*The Secretary*  
 7           *shall remove from the listing under paragraph (1)—*

8                   “(A) *an entity with respect to which the*  
 9                   *Secretary has accepted an initial certification*  
 10                  *pursuant to subsection (a)(2)(A) and which does*  
 11                  *not submit a supplemental certification pursu-*  
 12                  *ant to subsection (a)(2)(B) that is accepted by*  
 13                  *the Secretary;*

14                  “(B) *an entity whose certification expires*  
 15                  *and which does not submit a renewal applica-*  
 16                  *tion that is accepted by the Secretary; and*

17                  “(C) *an entity with respect to which the*  
 18                  *Secretary revokes the Secretary’s acceptance of*  
 19                  *the entity’s certification, pursuant to subsection*  
 20                  *(d).*

21           “(d) *REVOCATION OF ACCEPTANCE.*—

22                  “(1) *IN GENERAL.*—*Except as provided in para-*  
 23                  *graph (2), if the Secretary determines that a patient*  
 24                  *safety organization does not perform any activity de-*  
 25                  *scribed in subparagraph (A) through (F) of section*

1       921(3), the Secretary may, after notice and an oppor-  
 2       tunity for a hearing, revoke the Secretary’s acceptance  
 3       of the certification of such organization.

4               “(2) *DELAYED CERTIFICATION OF COLLECTION*  
 5       *FROM MORE THAN ONE PROVIDER.*—A revocation  
 6       under paragraph (1) may not be based on a deter-  
 7       mination that the organization does not perform the  
 8       activity described in section 921(3)(B) if—

9               “(A) the listing of the organization is based  
 10       on its submittal of an initial certification under  
 11       subsection (a)(2)(A);

12              “(B) the organization has not submitted a  
 13       supplemental certification under subsection  
 14       (a)(2)(B); and

15              “(C) the 2-year period described in sub-  
 16       section (a)(2)(B) has not expired.

17       “(e) *NOTIFICATION OF REVOCATION OR REMOVAL*  
 18       *FROM LISTING.*—

19              “(1) *SUPPLYING CONFIRMATION OF NOTIFICA-*  
 20       *TION TO PROVIDERS.*—Within 15 days of a revocation  
 21       under subsection (d)(1), a patient safety organization  
 22       shall submit to the Secretary a confirmation that the  
 23       organization has taken all reasonable actions to no-  
 24       tify each provider whose patient safety data is col-

1       lected or analyzed by the organization of such revoca-  
2       tion.

3               “(2) *PUBLICATION.*—Upon the revocation of an  
4       acceptance of an organization’s certification under  
5       subsection (d)(1), or upon the removal of an organiza-  
6       tion from the listing under subsection (c)(2), the Sec-  
7       retary shall publish notice of the revocation or re-  
8       moval in the *Federal Register*.

9               “(f) *STATUS OF DATA AFTER REMOVAL FROM LIST-*  
10      *ING.*—

11              “(1) *NEW DATA.*—With respect to the privilege  
12      and confidentiality protections described in section  
13      922, data submitted to an organization within 30  
14      days after the organization is removed from the list-  
15      ing under subsection (c)(2) shall have the same status  
16      as data submitted while the organization was still  
17      listed.

18              “(2) *PROTECTION TO CONTINUE TO APPLY.*—If  
19      the privilege and confidentiality protections described  
20      in section 922 applied to data while an organization  
21      was listed, or during the 30-day period described in  
22      paragraph (1), such protections shall continue to  
23      apply to such data after the organization is removed  
24      from the listing under subsection (c)(2).

1       “(g) *DISPOSITION OF DATA.*—If the Secretary revokes  
 2   the acceptance of an organization’s certification under sub-  
 3   section (d)(1) and removes the organization from the listing  
 4   as provided for in subsection (c)(2), with respect to the pa-  
 5   tient safety data that the organization received from pro-  
 6   viders, the organization shall—

7               “(1) with the approval of the provider and an-  
 8       other patient safety organization, transfer such data  
 9       to such other organization;

10              “(2) return such data to the provider of that pa-  
 11      tient safety data; or

12              “(3) if returning such data to the provider is not  
 13      practicable, destroy such data.

14   **“SEC. 925. TECHNICAL ASSISTANCE.**

15       “The Secretary, acting through the Director, may pro-  
 16   vide technical assistance to patient safety organizations, in-  
 17   cluding annual meetings for patient safety organizations  
 18   to discuss methodology, communication, data collection, or  
 19   privacy concerns.

20   **“SEC. 926. PROMOTING THE INTEROPERABILITY OF**  
 21               **HEALTH CARE INFORMATION TECHNOLOGY**  
 22               **SYSTEMS.**

23       “(a) *DEVELOPMENT.*—Not later than 36 months after  
 24   the date of enactment of the Patient Safety and Quality  
 25   Improvement Act of 2003, the Secretary shall develop or

1 *adopt voluntary national standards that promote the elec-*  
 2 *tronic exchange of health care information.*

3 “(b) *UPDATES.*—*The Secretary shall provide for the*  
 4 *ongoing review and periodic updating of the standards de-*  
 5 *veloped under subsection (a).*

6 “(c) *DISSEMINATION.*—*The Secretary shall provide for*  
 7 *the dissemination of the standards developed and updated*  
 8 *under this section.*

9 **“SEC. 927. AUTHORIZATION OF APPROPRIATIONS.**

10 “*There is authorized to be appropriated such sums as*  
 11 *may be necessary to carry out this part.*”.

12 **SEC. 4. STUDIES AND REPORTS.**

13 (a) *IN GENERAL.*—*The Secretary of Health and*  
 14 *Human Services shall enter into a contract (based upon*  
 15 *a competitive contracting process) with an appropriate re-*  
 16 *search organization for the conduct of a study to assess the*  
 17 *impact of medical technologies and therapies on patient*  
 18 *safety, patient benefit, health care quality, and the costs of*  
 19 *care as well as productivity growth. Such study shall exam-*  
 20 *ine—*

21 (1) *the extent to which factors, such as the use*  
 22 *of labor and technological advances, have contributed*  
 23 *to increases in the share of the gross domestic product*  
 24 *that is devoted to health care and the impact of med-*  
 25 *ical technologies and therapies on such increases;*

1           (2) *the extent to which early and appropriate in-*  
2           *troduction and integration of innovative medical*  
3           *technologies and therapies may affect the overall pro-*  
4           *ductivity and quality of the health care delivery sys-*  
5           *tems of the United States; and*

6           (3) *the relationship of such medical technologies*  
7           *and therapies to patient safety, patient benefit, health*  
8           *care quality, and cost of care.*

9           (b) *REPORT.*—*Not later than 18 months after the date*  
10          *of enactment of this Act, the Secretary of Health and*  
11          *Human Services shall prepare and submit to the appro-*  
12          *priate committees of Congress a report containing the re-*  
13          *sults of the study conducted under subsection (a).*





**Calendar No. 387**

108TH CONGRESS  
1ST SESSION

**S. 720**

**[Report No. 108–196]**

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**A BILL**

To amend title IX of the Public Health Service Act  
to provide for the improvement of patient safety  
and to reduce the incidence of events that ad-  
versely effect patient safety.

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NOVEMBER 17, 2003

Reported with an amendment